UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 99-CV-2496 (GK)
	)	
PHILIP MORRIS USA INC. (f/k/a PHILIP MORRIS INCORPORATED), et al.,	)	
	)	
Defendants.	)	

UNITED STATES' WRITTEN DIRECT EXAMINATION OF

MICHAEL C. FIORE, M.D., M.P.H

SUBMITTED PURSUANT TO ORDER #471

Q: Please state your name for the record.

A: Michael C. Fiore.

Q: Dr. Fiore, what is your current professional position?

A: I am a Professor of Medicine and the Director of the Center for Tobacco Research and Intervention at the University of Wisconsin Medical School in Madison, Wisconsin.

Q: I'd like to start by asking you about your educational and professional background. First, where did you receive your professional education?

A: I graduated Magna Cum Laude from Bowdoin College in Brunswick, Maine, in 1976 and then completed medical school at Northwestern University, earning a Doctor of Medicine degree in 1981. I also obtained a Masters of Public Health in Epidemiology from the Harvard University School of Public Health in 1985.

Q: What professional positions have you held?

A: I completed my internship and residency immediately after medical school in internal medicine at Boston Hospital. It was at the end of that time period that I applied to the Masters of Public Health program at Harvard University. I completed that program and received my M.P.H. in Epidemiology, as I mentioned, in 1985. Immediately after that, I began service as an Epidemic Intelligence Service (EIS) officer with the Centers for Disease Control and Prevention (CDC).

Q: What is the Epidemic Intelligence Service?

A: EIS is the country's leading epidemiology training service, serving as a premier surveillance and response unit for all types of epidemics, including chronic disease and injuries. It was established in 1951 following the start of the Korean War as an early warning system against biological warfare and epidemics. The EIS program is composed of medical doctors,

researchers, and scientists interested in the practice of epidemiology who serve two year assignments as part of a surveillance and response system for all types of epidemics, including chronic diseases and injuries. Since the program's establishment in 1951, EIS officers have worked on more than 10,000 studies and investigations; they assist with approximately 100 investigations requested by states and other countries each year; and field officers assigned to state and local health departments conduct an average of 500 studies and consultations per year.

Q: Was your work at EIS related to your training in epidemiology at Harvard?

A: Yes, it was. The work of the EIS is based on epidemiology, as it concerns the study of the distribution and determinants of disease in populations – that is, the EIS seeks to understand what causes disease, and where and how disease occurs. Historically, EIS officers have been involved in seeking to contain or eradicate diseases like polio and smallpox, addressing lead exposure, and investigating the earliest HIV/AIDS cases in the 1980s. EIS officers have also been involved in tobacco control efforts.

Q: How are EIS officers appointed?

A: After selection through a competitive application process, EIS officers are appointed by CDC to do epidemiological work in Atlanta at CDC headquarters or around the country on a two year appointment that starts each July 1. When I was chosen to be an EIS officer, the incoming class gathered in Atlanta in April prior to the start of the two year term for EIS's week-long annual conference. While there, we met with program officials within CDC and various state health departments. The members of the incoming class rank the programs of interest to them and there is a computerized match, somewhat similar to the match that occurs each year for medical students who are going into residency programs. CDC then announces the match one evening toward the end of the annual April conference.

Q: Where did you wind up working after the match?

A: During my service as an EIS officer, I worked for the Section of Environmental and Chronic Disease Epidemiology at the Wisconsin Division of Health, where my work centered on environmental and chronic disease issues. Specifically, I studied the health effects of groundwater pesticide contamination and the health effects of "tight homes" – prefabricated homes with limited ventilation that are sometimes associated with mold and other allergen growth. I also did clinical work with internal medicine patients each week while serving as an EIS officer.

Q: What did you do professionally at the end of your two-year EIS appointment?

A: During my two years as an EIS officer, I was selected by the CDC to stay on as one of approximately 20 EIS officers who were invited to receive additional preventive medicine training and experience. In this new capacity, I worked as a medical epidemiologist and preventive medicine resident from 1987-1988 at CDC's Office on Smoking and Health in Rockville, Maryland.

Q: Please tell the Court about your work at the Office on Smoking and Health.

A: I worked with the epidemiology group at the Office on Smoking and Health, which at that time had about 5 epidemiologists. My research, along with the group, focused on the epidemiology of tobacco use and the impact of public health policies on tobacco use. My colleagues and I analyzed data from the National Health Interview Surveys (NHIS), among others, to assess trends in tobacco use starting in the mid-1960s and projecting cigarette smoking prevalence to the year 2000.

We also studied tobacco use prevalence and ascertained that disparities that had developed over time as a function of educational and socioeconomic status. That is, if you were

less educated, you were more likely to smoke compared to those with at least a high school education. The findings of these analyses were published in the *Journal of the American Medical Association* (JAMA) in 1989. As part of this three paper series in JAMA, my colleagues and I also analyzed data from the NHIS since the mid-1960's and documented that the smoking prevalence among men was decreasing at four times the rate of women.

Additionally, we analyzed data from the 1986 Adult Use of Tobacco Survey to understand how smokers actually attempt to quit smoking. We learned that, in 1986, 80% to 90% of smokers who tried to quit reported they had used a "cold turkey" method – that is, on their own without any evidence-based treatment. At that time, few science-based treatments were available – nicotine gum was the only medication that had been approved by the FDA and little was known about effective counseling approaches. These findings were published in JAMA in 1990.

Q: How long did you remain at the Office on Smoking and Health?

A: I stayed at OSH until 1988, when I joined the faculty at the University of Wisconsin Medical School as an Assistant Professor of Medicine.

Q: Describe your work as an assistant professor.

A: My position in the Department of Medicine as an assistant professor focused on two areas: first, I worked as a licensed and board certified internist, providing primary care and preventive medicine care, including the clinical treatment of patients addicted to tobacco, at University of Wisconsin Hospitals and Clinics; second, I engaged in research and intervention activities around tobacco and continued a research career in tobacco, building on work that I had begun at OSH. In fact, during the first couple of years that I was at Wisconsin, I returned to OSH several times each year to collaborate with colleagues there.

Q: Please tell the Court about your involvement in the clinical treatment of patients addicted to tobacco.

A: Soon after joining the faculty at the University of Wisconsin Medical School, patients who smoked began to make appointments in my internal medicine clinic looking for help in quitting. I remember the first patient who I will call "Sandy" (name and personal information changed to protect patient confidentiality). This patient convinced me that I needed to become an expert in treating tobacco dependence as well as an expert tobacco control researcher. Sandy, a middle-aged woman who smoked about a pack of cigarettes each day and had tried unsuccessfully more than a dozen times to quit on her own, came to me asking for help. I told her that day that I would work with her to help her achieve her goal. Sandy was particularly committed to doing this because her daughter had learned a few months before that she was pregnant and Sandy wanted her first grandchild to be born to a smokefree grandma. I provided counseling and put Sandy on nicotine gum, the only medicine available at the time. Although it was incredibly difficult for her, Sandy was able to successfully quit. During her last scheduled smoking cessation visit with me, Sandy told me about a persistent cough over the previous month and an episode the week before of coughing up a small amount of blood. Because of the ominous implication of this (hemoptysis), I sent her for an immediate x-ray and was horrified to see that she had an orange sized tumor in one of her lungs.

While she fought heroically, Sandy was killed by her smoking-induced lung cancer within about eight months. About two months before she died, she visited me for the last time, mostly to let me know that she had stayed quit and that her first granddaughter had been born to a smokefree grandma. This experience had an enormous impact on me and soon thereafter, I established the University of Wisconsin Smoking Cessation and Prevention Clinic, which has

been helping smokers who want to quit to do so successfully since that time.

Q: Have you remained at the University of Wisconsin Medical School since 1988?

A: Yes. I was promoted to Associate Professor in 1994 and Professor in 1998. I also founded and have served as Director for the Center for Tobacco Research and Intervention since it was established in 1992. In addition, I was a member of the U.S. Army Reserve from 1990-1992, including a period on active duty from 1990-91 during the Persian Gulf War.

Q: Before we discuss the Center for Tobacco Research and Intervention, can you tell the Court generally about the focus of your research at the University of Wisconsin?

A: Certainly. My research at the University of Wisconsin has focused on understanding tobacco dependence and developing effective strategies, both clinical and population-based, to facilitate treatment of tobacco dependence.

Q: How have you researched the issue of tobacco dependence?

A: One area of my research in understanding tobacco dependence has focused on the tobacco withdrawal syndrome as an explanatory measure for how treatments work and why, in some instances, they may not be as effective. My colleagues and I developed and tested novel measures of and approaches to withdrawal and dependence that were more sophisticated and sensitive than those used in previous studies. These measures revealed that withdrawal symptoms sometimes last much longer than was suggested by earlier work, that different components of the withdrawal syndrome were highly predictive of likelihood of treatment failure, and that efficacious pharmacotherapies work in part by suppressing these components of the withdrawal syndrome.

Q: What is the significance of this type of research for understanding tobacco dependence?

A: This research is of great importance since it shows a natural history and duration of withdrawal symptoms that would not have been predicted by previous studies; in fact, some smokers who quit have more severe withdrawal symptoms two to three months after they quit than they did in their first week after quitting. Further, these findings support our understanding that withdrawal symptoms are important causes of treatment failure and relapse. Finally, this research suggests particular targets and components of the withdrawal syndrome that can be targeted by new treatments. These findings have been published in a series of papers in the *Journal of Abnormal Psychology* and the journal *Addiction,* among others.

Q: How has your research addressed the issue of developing effective clinical strategies for smoking cessation?

A: In the early 1990s, there were clear data indicating that most clinicians were neither identifying smokers nor providing cessation treatment in the course of health care delivery. Moreover, a number of traditional educational strategies such as continued medical education had proven to be an ineffective stand-alone strategy for boosting clinicians' tobacco intervention activities. Since tobacco use is the number one preventable cause of morbidity and mortality in the United States, this represented a major missed opportunity for clinicians to improve their patients' health. Therefore, in 1991, I wrote a commentary in JAMA that urged that smoking status be added to the four vital signs (pulse, respiration, blood pressure and temperature) that are routinely checked in a doctor's office. This was a bold proposal; the original four vital signs had been in place for decades. But this represented a no-cost strategy to integrate tobacco use assessment seamlessly into the normal course of health care delivery.

Over the coming years, I not only promoted this strategy but conducted research to evaluate its acceptability and impact in clinical settings. This research by me and others found that

expanding the vital signs to include smoking status increased the rate that smokers who present to clinics are identified and the rate that clinicians talked about tobacco use to their patients. This work was published *Mayo Clinic Proceedings* in 1995.

As a result of these research efforts, the use of the expanded vital signs has been adopted by the Veterans Administration health care facilities and was incorporated into the recommendations of the 1996 Agency for Health Care Policy and Research (AHCPR) Smoking Cessation Guideline (#18) and the 2000 U.S. Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence.* Further, measurement of asking patients about their tobacco use as part of routine medical care has been incorporated into the National Committee for Quality Assurance's (NCQA) Health Plan Employer Data and Information Set (HEDIS) measures. These data are used as part of managed care report cards to help purchasers of health care and consumers determine which managed care plans provide the highest quality services.

Q: Can you describe some of the other research you have conducted while at the University of Wisconsin?

A: I have been involved in many studies of pharmaceutical treatments for smoking cessation, both as a Principal Investigator and as a co-investigator. My colleagues and I have performed some of the first research on the clinical efficacy of nicotine replacement therapies and bupropion SR (which was first sold as Zyban®). This research has been published in JAMA, the *New England Journal of Medicine* and elsewhere and has been widely cited by other researchers and in authoritative reviews. Among the principal information obtained from this research are the following: (1) efficacy estimates for specific pharmacotherapies – estimates that have been replicated by numerous other investigators; (2) specific strategies that lead to optimal success when using these pharmacotherapies, including which treatments are best for which

populations (e.g., women, those with a history of depression); (3) the effectiveness of combining pharmacotherapy and behavioral counseling and the mechanisms by which they work; and (4) the cost-effectiveness of pharmacotherapies, counseling, and their use in combination.

Q: Why is the issue of cost-effectiveness important?

A: The issue of cost-effectiveness is important to encourage the more widespread provision of treatment for tobacco dependence. Adoption of medical interventions is often delayed until the cost-effectiveness of an intervention compared with other known interventions can be demonstrated. My work with Dr. Jerry Cromwell documented that the clinical treatment of tobacco dependence – including pharmacotherapies, counseling, and their use in combination – is cost-effective in ways comparable to other routine medical interventions, such as mammography screening ,coronary artery bypass graft surgery and the use of beta blockers in patients after a heart attack. This research was published in JAMA in 1997.

Q: What other work in the field of smoking cessation have you done during the time you have been at the University of Wisconsin?

A: I chaired the panels that produced the Agency for Health Care Policy and Research (now called the Agency for Healthcare Research and Quality, or AHRQ) Clinical Practice Guideline (#18), *Smoking Cessation* in 1996 and the United States Public Health Service Clinical Practice Guideline: *Treating Tobacco Use and Dependence* in 2000. I also chaired the United States Department of Health and Human Services Subcommittee on Cessation of the Interagency Committee on Smoking and Health, which in 2003 produced a National Action Plan for promoting tobacco cessation in the United States. I also chaired the United States Health Care Financing Administration (HCFA) Expert Panel on Interventions to Promote Smoking Cessation in the Medicare Population.

Q: I want to ask you questions about the Clinical Practice Guidelines at greater length when we address the substance of your opinions. We will also address the National Action Plan within that context. First, however, I want to focus on the University of Wisconsin Center for Tobacco Research and Intervention. To start, what is the Center?

A: The University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) is a Center within the University of Wisconsin Medical School. Centers are organizational units within the University that are established to address a specific problem or issue – in this case, tobacco dependence. UW-CTRI was established in 1992 after then-University Chancellor Donna Shalala proposed that the tobacco research program that I had established and led at the time be formally designated as the lead university entity responsible for the topic. Centers typically exist for specific time frames; in this case, the time frame for UW-CTRI's existence is until we eliminate the harms resulting from tobacco use.

Q: Does UW-CTRI have a specific mission?

A: It does. The UW-CTRI mission is: "To expand our understanding of tobacco dependence and its treatment and to use this knowledge to design and implement interventions that will significantly reduce tobacco use in Wisconsin, the nation, and beyond." Our primary goal is to help smokers quit.

Q: How has UW-CTRI sought to achieve this primary goal?

A: My colleagues and I have created a diverse portfolio of research, outreach and intervention programs, policy activities, and direct services to smokers in order to help us both fulfill our mission and achieve our primary goal. UW-CTRI provides services to thousands of Wisconsin residents through its outreach program and its Wisconsin Tobacco Quit Line, which provides telephonic cessation counseling services to Wisconsin residents. The Center is

currently involved in clinical trials of medications under development by the pharmaceutical industry, namely rimonabant, varenicline, and the nicotine vaccine. In the past, UW-CTRI also conducted clinical trials on the nicotine patch, bupropion and other medications that could aid in the treatment of tobacco dependence. Through its federal and foundation grants and its clinical trials, the Center has brought more than $30.4 million in research funding – primarily federal grants – to Wisconsin. We continue to focus on tobacco treatment in both the research conducted by the Center and our Wisconsin outreach program: new studies are designed to better match individuals and their treatments and a focus on long term outcomes of quitting, and the Center's future goals include working to increase quit rates to 50 percent or greater and developing treatments that can be better matched to individual differences such as gender and racial and ethnic status.

Q: How large an organization is UW-CTRI?

A: UW-CTRI has grown from a staff of about five in the early 1990s to an organization of over 70. In 1992, when UW-CTRI was first established, research into the treatment of tobacco dependence was in its early stages. The Surgeon General had released his Reports on Nicotine Addiction in 1988 and on The Health Benefits of Smoking Cessation in 1990, and scientists were looking for new ways to help people quit smoking. Physicians were exploring how to deliver these treatments and how the larger community might discourage smoking. UW-CTRI programs were at the forefront of this effort, which we have expanded significantly over the past 13 years.

Q: Tell the Court more about current programs at UW-CTRI.

A: UW-CTRI's current programs can be separately by primary emphasis – national, state, and local. National initiatives include a number of research and policy programs designed to address the larger issues in tobacco control. At its core, UW-CTRI science is focused on its

federally funded peer-reviewed research and on developing evidence-based policy proposals that promote tobacco cessation as well as guidelines for clinical treatment. Among the research topics that the National Institutes of Health and other federal agencies have funded at UW-CTRI are research into the powerful role of clinicians in motivating smokers to quit, systems-level changes that increase the rate of helping smokers to quit, and detailed analyses of the nature of tobacco dependence and its treatment. As I mentioned, we also do clinical trials of new smoking cessation medicines. In 1999, the National Cancer Institute and the National Institute on Drug Abuse joined together to support the establishment of Transdisciplinary Tobacco Use Research Centers (TTURC). These NIH Center grants were established to support state-of-the-art tobacco research, and UW-CTRI was selected as one of only seven across the nation. I served as Principal Investigator on the first UW-CTRI TTURC.

At the state level, we work to address the profound death and suffering from tobacco use in Wisconsin. Similar to national statistics, over 70 percent of Wisconsin smokers want to quit and close to 50 percent try to quit each year. UW-CTRI runs a statewide outreach program to train clinicians across the state to more effectively help their patients to quit smoking and to change the health systems in which they work to insure that every smoker is provided with evidence-based treatments. We have worked with more than 10,000 clinicians across the state to achieve this goal.

At the local level, one of UW-CTRI's first programs, the Smoking Cessation and Prevention Clinic, continues to offer comprehensive clinical services to help people stop smoking. The clinic, located at the UW-CTRI offices in Madison, is run by a staff of clinical psychologists, physicians, and others who are experts in the field of smoking cessation. Clinic staff members help smokers understand the physical and psychological aspects of quitting

smoking and help them use a variety of strategies to successfully quit.

Q: Dr. Fiore, have you previously undertaken research sponsored by pharmaceutical companies?

A: Yes. As I mentioned earlier, UW-CTRI is the lead campus agency at the University of Wisconsin Medical School which has as its charge understanding and treating tobacco dependence in society. One activity as part of our research activities over the years has been to occasionally conduct research that has been sponsored by the pharmaceutical industry including research sponsored GlaxoSmithKline, Pfizer, Sanofi, Ciba-Geigy, and Elan. In terms of the amount of funding, we just published our annual report for 2004, and in that year with a total budget of slightly over $6 million for the Center, pharmaceutical research funding accounted for about 16 percent of the budget.

Q: Is your compensation from your work at the University of Wisconsin Medical School and CTRI tied to pharmaceutical research funding?

A: No, not at all. I receive a salary from the University for my work as a professor and my clinical activities. Those responsibilities include my work as director of CTRI, and there is no salary component tied to the research dollars that CTRI receives from outside sources. Separately, I have done some consulting work for pharmaceutical companies over the years. Over the past five years, my outside consulting work on an annual basis has ranged between about $10,000 and $30,000 or $40,000 per year.

Q: I understand that GlaxoSmithKline established a chair for the treatment of tobacco dependence at the University of Wisconsin, and that you hold that chair?

A: That is correct.

Q: Please tell the Court what that funding provides.

A: GlaxoSmithKline gave a grant to the University of Wisconsin that established a chair for the treatment of tobacco dependence. That donation by GlaxoSmithKline was to the University. Named chairs at the University of Wisconsin provide the person who sits in that chair to access to the revenue generated from the investment on the initial grant. So in this instance, I have access to up to $50,000 per year to support my University approved and sanctioned educational, research, and policy activities.

Q: Continuing to discuss your professional background and experience, have you directed any grants or foundations?

A: Yes. I have served as Principal Investigator and have directed a number of grants. As an example, I have been the Director of the Robert Wood Johnson Foundation National Program Office – Addressing Tobacco in Managed Care since 1996. This program provides grants to evaluate the effectiveness of systems-level interventions designed to increase the identification of and intervention with tobacco users who present to health care settings. From 1999-2004, I served as Principal Investigator on the NIH Transdisciplinary Tobacco Use Research Center (TTURC) Grant, *Relapse: Linking Science and Practice*. Since 2004, I have been the Co-Principal Investigator on a new NIH TTURC Grant, *Tobacco Dependence: Treatment and Outcomes.*

Q: Do you have any specialty board certifications?

A: Yes. I am certified in Internal Medicine by the American Board of Internal Medicine and am board eligible in Preventive Medicine by the American Board of Preventive Medicine.

Q: Do you still treat patients?

A: Yes, I do. I am active in clinical practice as a General Internist and have been continuously since arriving at the University of Wisconsin in 1988. Currently, I see patients one

day per week at a University of Wisconsin General Internal Medicine Clinic in Madison. Additionally, I serve as one of the in-patient Attending Physicians at the University of Wisconsin Hospital each year, taking care of hospitalized patients. I also supervise internal medicine residents at the clinic. I see patients who seek care at the UW-CTRI Smoking Cessation and Prevention Clinic one half-day each week. Last, I provide medical supervision for participants in our clinic trials at UW-CTRI.

Q: Have you received any awards for your professional work?

A: Yes, I have.

Q: Are there particular awards that you would like to highlight for the Court?

A: One of the awards that I am most proud of is the Doll/Wynder Award for Research in Epidemiology and Public Health from the Society for Research on Nicotine and Tobacco, which is awarded once every three years for substantial contributions to tobacco control research and practice. I also received the Innovators Combating Substance Abuse Award, in recognition of substantial and innovative contributions to the field of substance abuse prevention, sponsored by the Robert Wood Johnson Foundation; the United States Surgeon General's Certificate of Appreciation, for serving as chairman of the first and second Clinical Practice Guidelines on Tobacco Cessation and for exceptional leadership in disseminating the Guidelines; and the Presidential Citation Award from the State Medical Society of Wisconsin for serving on active duty during the Persian Gulf War.

Q: Are you a member of any professional organizations?

A: Yes. I am a member of the American Medical Association, the American Public Health Association, the Society of General Internal Medicine, the Society for Research on Nicotine and Tobacco, the American College of Preventive Medicine, and the American Society of Preventive

Oncology.

Q. Do you serve as a journal reviewer for any medical peer review publications?

A: I do. I have been a reviewer for the *American Journal of Preventive Medicine*, *CHEST*, the *Journal of the American Medical Association*, the *Journal of the National Cancer Institute*, *Mayo Clinic Proceedings*, the *New England Journal of Medicine*, *Nicotine and Tobacco Research*, *Preventive Medicine*, *Public Health Reports*, and *Tobacco Control*.

Q: Dr. Fiore, have you ever testified in Court before?

A: No, I have not. I did provide a deposition as an expert witness in a tobacco case in New York in 1996, but that is the only time I have testified in a litigation proceeding before this.

I am asked to testify by plaintiffs against tobacco companies many times each year, but I have chosen to concentrate instead on the clinical and research work that has been the focus of my career for two decades.

Q: Why did you agree to serve as an expert witness for the United States in this case?

A: I feel that I have an obligation to assist the United States of America in what I believe is an extraordinarily important effort to provide barrier-free access to cessation treatments for all Americans, regardless of geographic location, socioeconomic status, or background.

II. OVERVIEW OF OPINIONS

Q: Dr. Fiore, in your opinion, is there a need for a comprehensive national smoking cessation program?

A: Yes. Reducing tobacco use is a public health issue of paramount and unparalleled importance. There is a substantial body of evidence documenting the toll that tobacco exacts in terms of years of life lost, excess health care costs, and other excess costs, such as lost productivity. Just as importantly, there are millions of smokers who want to quit but continue to

smoke. A comprehensive national smoking cessation program has the potential to reach smokers of diverse populations, to normalize quitting, and to make sure that every smoker who wishes to quit has the opportunity to do so successfully using science-based treatments.

Q: Please provide the Court a general overview of what a comprehensive cessation program should address.

A: It is important that a comprehensive cessation program provide a full range of treatment options, both counseling and medications, so that treatments can be targeted to the needs of individual smokers. Moreover, it creates an environment that encourages quitting through a multifaceted media campaign, it includes a health care delivery system that includes clinicians who are trained and equipped in tobacco dependence treatments, and it supports a research infrastructure that identifies new treatments that assist all smokers to quit successfully – even those who haven't yet been able to quit with the currently available treatments. A comprehensive cessation program should also address disparities in tobacco use. Scientific data show that persons of lower socioeconomic status, lower educational attainment, and certain racial and ethnic minorities smoke at much higher rates than the general population in the United States. Such groups suffer disproportionately from the excess illness and death from tobacco use. A national cessation initiative should be designed to benefit all tobacco users and their families to help address these disparities. With a full range of treatment options and a program that reaches all smokers, we can help at least 1 million new smokers quit the use of tobacco successfully each year. And if the program exists for at least 25 years, we can work to help all smokers who wish to quit but are unable to do so.

Q: At the outset of your testimony on a comprehensive cessation program, can you briefly identify for the Court the key features of such a program?

A: Yes. The key components of a comprehensive, evidence-based cessation program are: (1) a national tobacco quitline network that will provide universal, barrier-free access to evidence-based counseling and medications for tobacco cessation; (2) an extensive paid media campaign to encourage all smokers in the United States to quit using tobacco; (3) a new, broad, and balanced research agenda (basic, clinical, public health, translational, dissemination) to achieve future improvements in the reach, effectiveness and adoption of tobacco dependence interventions across both individuals and populations; and (4) training and education to ensure that all clinicians in the United States have the knowledge, skills and support systems necessary to help their patients quit tobacco use.

A comprehensive cessation program should also: (5) mobilize health systems to implement system-level changes that result in effective utilization of tobacco dependence treatments; (6) mobilize national quality assurance and accreditation organizations, clinicians, health systems, and others to establish and measure the treatment of tobacco dependence as part of the standard of care; and (7) mobilize communities to ensure that policies and programs are in place to increase demand for services and to ensure access to such services. In my view, a fully funded, comprehensive smoking cessation program will prompt some of the public-private mobilization efforts to occur.

These components are based upon the best scientific evidence available and hold tremendous promise for producing dramatic decreases in tobacco use and its resulting human and economic costs.

In addition, each of the components of a comprehensive cessation initiative must be objectively evaluated to ensure that the activities undertaken are having their intended impact. It would not serve anyone well, particularly the tobacco users who are the intended beneficiaries of

such an initiative, if the activities undertaken are not effectively reaching them and facilitating tobacco use cessation.

A comprehensive cessation initiative should be sustained over time and securely funded. The best-designed initiative has little likelihood of being implemented and having sustained impact without a secure, ongoing funding source. Secure and sustained funding is also important to permit both short- and long-term evaluation of such initiatives to ascertain whether they are having their intended effect on the population.

One very important point is that to maximize their effectiveness, the different parts of a comprehensive program must be integrated and viewed as interdependent parts. While each component I have recommended to the Court has a substantial science base documenting its independent effectiveness, integrated together, this comprehensive program can dramatically reduce tobacco use rates.

Q: Why do you consider it to be important to integrate the different components of the plan?

A: Real-world experience of people directing smoking cessation programs and clinics in different states and regions, including our program in Wisconsin, shows that the different parts of an comprehensive program are more effective when applied in tandem with other components of the program. At that same time, evidence shows that every component that I have recommended to the Court will by itself result in reductions in tobacco use rates. However, experience with state and local programs has shown that when more than one of these components are integrated, the reach, in terms of the number of smokers treated, and the outcomes, in terms of long term quit rates, are markedly increased.

Q: On what basis do you include specifically identified components?

A: Components of a national cessation initiative should be based upon the best available science, to ensure that the resources applied to this initiative are used in a way that is supported by the evidence. Each of the elements that I have identified is included because it is supported by a strong base of scientific evidence. Based on an extraordinarily large body of scientific evidence and experience, we know what works in terms of programs and initiatives to foster effective tobacco dependence treatment.

Q: In your view, who should be eligible to participate in the cessation program – that is, what should be the criteria to assess whether a person is a smoker who "qualifies" to obtain cessation assistance from the program?

A: Every smoker in the United States should be eligible to participate. Having barrier-free access to evidence-based smoking cessation therapy is absolutely essential if a program is going to reach the largest number of smokers and thereby help the maximum number of smokers to quit. One of the reasons that comprehensive smoking cessation treatment is so underutilized in this country is that there are often barriers to use even where services are offered. Barriers may take the form of eligibility requirements, screening processes, co-payment obligations, language and other cultural barriers, limited access to services, lack of awareness, limits to covered benefits, and fragmentation of care.

Q: What is the total cost associated with the comprehensive cessation program you have outlined?

A: Drawing on the conclusions and calculations of the Cessation Subcommittee of the United States Interagency Committee on Smoking and Health, a comprehensive cessation program should be funded at the level of $5.2 billion annually. It is important to note that the Subcommittee relied on scientific

evidence, testimony from experts, and cost information from similar programs in estimating the costs associated with the recommendations discussed in my testimony. In some instances, a specific cost estimate was not derived, as the Subcommittee did not have reliable cost estimates in order to make a recommendation for funding or because those recommendations challenge the private sector to take steps to support tobacco dependence treatment.

Q: What would you anticipate the reach to be for a comprehensive cessation program with a $5.2 billion annual budget?

A: At that level of funding, we would have the capacity to have 16% of smokers who want to quit access the services of the program annually, with 10% of smokers actually utilizing some level of counseling and medications.

Q: Dr. Fiore, I'd like to ask you questions about the different components of the program. Before we go through them, however, it is my understanding that the Cessation Subcommittee of the Interagency Committee on Smoking and Health, which you chaired, looked at the question of what was needed in order to help smokers quit tobacco use in America.

A: That is correct.

Q: How did you come to be the Chair of that Subcommittee?

A: On August 14, 2001, I was asked to participate in a meeting of the Interagency Committee on Smoking and Health (ICSH), chaired by Surgeon General David Satcher, M.D., Ph.D. The focus of the meeting was tobacco use cessation. I was asked to attend this ICSH meeting and to give closing comments at the end of day, synthesizing the remarks that had been made and the discussion that had occurred. The day was inspiring, and many good ideas for facilitating tobacco use cessation were discussed. In my closing remarks, I asked the Surgeon

General not to let the important work from the day just be summarized in a report that would sit on the shelf; rather, I asked that he and the Secretary of the Department of Health and Human Services, Tommy Thompson, take action to implement the ideas that had been discussed that day to help facilitate tobacco use cessation.

Q: Did you receive a response to your remarks?

A: I did. At the end of the meeting, the Surgeon General responded that the Secretary had a keen interest in this area and asked me to join him in Washington, DC, when he would formally present the report of the meeting to the Secretary and ask him to take action. I was honored to accept his invitation.

In early 2002 – I believe in February – I traveled to Washington, DC, for this meeting. The Secretary was very complimentary of Dr. Satcher's work and the ICSH's focus on tobacco use cessation. During the meeting, the Secretary requested that a Subcommittee of the ICSH be formed to create a set of evidence-based strategies that would have a powerful impact and help smokers across America successfully quit tobacco use. He asked me to chair this Subcommittee, and asked the Surgeon General to serve as a member of the Subcommittee (at the time of the meeting, Surgeon General Satcher had announced his resignation from federal service). We both agreed to do so.

Q: What happened next?

A: In order to chair a subcommittee, I had to first be appointed to the parent committee, that is, the full ICSH. That process began in spring 2002 and the nomination process was completed in the summer of 2002.

Q: What was your first primary task once you were in place as Chair of the Subcommittee?

A: I worked with the ICSH staff – the Subcommittee was staffed by the CDC's Office on Smoking and Health – to propose a list of panel members, which was submitted for consideration to Michael Schooley, the Executive Secretary of the ICSH. The 16-member panel that was selected for the Subcommittee on Cessation represented a broad array of scientists from a variety of disciplines, health policy makers, federal officials, and representatives from the health insurance and business group sectors. We thought very long and hard about what we needed in terms of representation on the Subcommittee in order to fulfill the charge that we received from Secretary Thompson. The diversity of perspectives and opinions as well as the extensive expertise of the Subcommittee members was essential to create a plan that was broad-based, involved calls to action for both the public and private sectors, and would ultimately be accepted by multiple constituencies in both the public and private sectors.

Q: Did you reach out to include any representatives from the tobacco industry for the panel?

A: No.

Q: Why not?

A: First, the Department of Health and Human Services, which selected the Subcommittee membership, did not suggest that the tobacco industry serve on the panel. Second, the mission of this panel – and all of the efforts in the cessation field – is to assist people to stop using cigarettes and other tobacco products. The tobacco industry manufactures and markets cigarettes. It would be fundamentally inconsistent with the mission and charge of the Subcommittee as given by Secretary Thompson to invite representatives from the tobacco industry to participate in this effort at the same time the industry continues to spend many billions of dollars each year marketing these products. Members of the tobacco industry were free, however, to come to the

public meetings of the Subcommittee – which were announced in the Federal Register – and present written or oral testimony for the Subcommittee's consideration in its work.

Q: Did any members of the tobacco industry do so?

A: No, they did not.

Q: Who were the members of the Subcommittee?

A: Dr. Robert Croyle, the Acting Director of the Division of Cancer Control and Population Sciences at the National Cancer Institute; Dr. Susan Curry, the Director of the Health Research and Policy Centers at the University of Chicago; Dr. Charles Cutler, the Chief Medical Officer of the American Association of Health Plans; Dr. Ronald Davis, the Director of the Center for Health Promotion and Disease Prevention at the Henry Ford Health System and member of the Board of Trustees of the American Medical Association; Catherine Gordon, Director, Health Promotion and Disease Prevention at the Center for Medicare and Medicaid Services; Dr. Cheryl Healton, President and CEO of the American Legacy Foundation; Rosemarie Henson, the Director of CDC's Office on Smoking and Health; Dr. Howard Koh, the Commissioner of Health for the State of Massachusetts; Dr. James Marks, the Director of the National Center for Chronic Disease Prevention and Health Promotion at CDC; Dr. Tracy Orleans, Senior Scientist of the Robert Wood Johnson Foundation; Dr. Dennis Richling, Assistant Vice President of Health Services for Union Pacific Railroad; former Surgeon General Satcher, who had by then become the Director of the National Center for Primary Care at the Morehouse School of Medicine; Dr. John Seffrin, the Chief Executive Officer of the American Cancer Society; Christine Williams, Director of the Office of Health Care Information at AHRQ; and Dr. Larry Williams, Captain in the Dental Corps of the United States Navy and the DOD/VA Primary Care Tobacco Use Cessation Champion. Michael Schooley of the CDC's Office on Smoking and

Health, whom I mentioned previously, served as Executive Secretary of the Subcommittee. The Subcommittee was supplemented by support staff that included Dr. Timothy Baker and Paula Keller from the UW-CTRI, and Jessica Porras and Monica Swann from the CDC's Office on Smoking and Health.

Q: You indicated that Secretary Thompson asked the Subcommittee to create a set of evidence-based strategies that would have a powerful impact and help smokers across America successfully quit smoking. What do you mean by "evidence-based?"

A: We were asked in preparing the National Action Plan to come up with a set of recommendations that would be first and foremost based on a solid scientific base. They would be based on a number of different studies and analyses that in a clear way pointed in a direction that could be used to construct a set of recommendations that would assist the Secretary as he attempted to reduce tobacco use rates in America. So evidence-based means it is published science, published in peer-reviewed journals, often multiple articles, often supported by meta-analyses – a large core body of scientific data. But it also, of course, includes the critical importance of bringing together experts in the field with their composite body of experience to comment on the science and to provide expert opinion. We expected the Subcommittee members to call upon their own research and other experience in the field – to bring that to the table in the process – and they did so. Finally, we had a broad and open process for obtaining input from experts and others with an interest in this topic to present their perspectives, either in person at the three regional meetings of the Subcommittee on Cessation (held in Denver, Chicago, and Washington, DC) or in writing.

Q: When did the Subcommittee first meet?

A: The Subcommittee first met on October 1, 2002, at the Department of Health and Human

Services' Hubert H. Humphrey Building in Washington, DC. At this meeting, the committee charge was given directly by Secretary of Health and Human Services, Tommy Thompson -- namely, to take the existing evidence base on effective cessation interventions, supplement it based on input from regional meetings, and develop an action plan for the Secretary that would dramatically increase rates of tobacco cessation in the United States and thereby reduce the enormous toll of illness, death, and cost that result from tobacco use in America. This action plan would serve as the basis for a Secretary's initiative on cessation beginning in 2003. The primary goals for the initiative were: to increase the number of quit attempts among the U.S. population of smokers, to encourage the use of evidence-based treatments that are under-utilized by those trying to quit, and to ensure such treatments are in fact readily accessible.

Q: What evidence did the Subcommittee look at in formulating the Action Plan?

A: In terms of existing literature, the Subcommittee looked specifically at the references that are cited at the end of the final draft of the Action Plan, and placed particular reliance on four evidentiary documents: the U.S. Public Health Services' Clinical Practice Guideline: *Treating Tobacco Use and Dependence* (JD 001210); the U.S. Task Force on Community Preventive Services' *Guide to Tobacco Use Prevention and Control* (Guide to Community Preventive Services) (U.S. Exhibit 64,554); the ICSH Action Plan on Tobacco Use Cessation report from August 2001, and the *Draft National Blueprint for Disseminating and Implementing Evidence-Based Clinical and Community Strategies to Promote Tobacco Use Cessation* (U.S. Exhibit 89,463).

Q: Did the panel also solicit information and input from other experts and the general public?

A: Yes. After the initial meeting at the Humphrey Building, three public hearings were held

across the country. The first public hearing was held on October 24, 2002, in Washington, DC; the second public hearing was held on November 14, 2002, in Denver, Colorado; and the third public hearing was held on December 3, 2002, in Chicago, Illinois. Each of these public meetings were announced in the Federal Register and they were designed to provide an opportunity for the public to provide input to the Subcommittee and supplement the extant evidence reviewed by the Subcommittee. In addition, the Federal Register announcements provided instructions to submit comments in writing. In total, approximately 100 individuals and organizations provided testimony in person and approximately 85 provided testimony in writing.

Q: Did you personally attend each of the three public hearings?

A: Yes, I did. I chaired the meetings.

Q: What did the Subcommittee do after the public hearings?

A: Following the public hearings, a final meeting was held on January 16, 2003, to come to consensus on the Subcommittee's recommendations. I then led the writing of the report of the Subcommittee, which was finalized and presented to Surgeon General, Richard Carmona, MD, MPH, FACS, as Chair of the ICSH on February 11, 2003. The ICSH that met on that day received the report, discussed its recommendations, and unanimously recommended the report be transmitted to the Secretary of Health and Human Services for his review and consideration.

Q: What were the panel's consensus recommendations?

A: The report, marked as U.S. Exhibit 89,464 and titled *Preventing 3 Million Premature Deaths, Helping 5 Million Smokers Quit: A National Action Plan for Tobacco Cessation* contained a set of ten recommendations: six federal, and four public-private partnership opportunities. The recommendations included: (1) establish a federally-funded National

Tobacco Quitline network to provide universal access to evidence-based counseling and medications for tobacco cessation; (2) launch an ongoing, extensive paid media campaign to help Americans quit using tobacco; (3) invest in a new, broad and balanced research agenda – including basic research, clinical research, public health research, translational research, and dissemination of research findings to achieve future improvements in the reach, effectiveness and adoption of tobacco dependence interventions across both individuals and populations; and (4) invest in training and education to ensure that all clinicians in the United States have the knowledge, skills and support systems necessary to help their patients quit tobacco use. We also recommended federal insurance coverage, public-private partnerships (including systems level changes and quality improvement strategies to expand the delivery of evidence-based tobacco dependence treatment), and tax initiatives.

III. NATIONAL SMOKING CESSATION PROGRAM

A. Telephone Quitline

Q: I want to turn to specific questions about the components of a national smoking cessation program that you are recommending to the Court, beginning with the telephone quitline. First of all, what is a telephone quitline as recommended?

A: A quitline provides telephone delivered, evidence-based counseling and medications to help smokers who want to quit to do that successfully. To access these treatments, a tobacco user calls a toll-free telephone number and speaks to a trained counselor, who provides information and assistance to the tobacco user in planning a quit attempt. Specifically, based on scientific evidence, the counseling discusses strategies that have been shown to increase the likelihood of successful cessation. But a quitline is not just a helpline; there are a number of essential components in order to insure effectiveness.

First, it is important that the quitline services (both counseling and medications) be available to all smokers, without any cost or insurance barriers. Counseling services should be of sufficient intensity to maximize chances of success. For this reason and based on research findings, it is recommended that counseling include at least four person-to-person, proactive calls from trained counselors. It is also important that quitline counseling is augmented with free FDA-approved pharmacotherapy (either over-the-counter medications or vouchers for prescription medications). And it is important that quitline services be tailored to the language, culture, and educational background of the user.

Another key feature of a quitline is having counselors who are trained to work with smokers to establish a detailed quitting plan, including the provision of specific advice on the types of medication that are most appropriate for the smoker in making the quit attempt. The trained counselors who staff the quitline should then be able to work with smokers both during the initial intake call and every step of the way through the process of quitting.

Additionally, it is important that telephonic treatment be available 24 hours per day, seven days a week, so that whenever a smoker wants to make an assisted quit attempt s/he is able to do so.

Q: Have quitlines been used previously?

A: Yes. The telephone quitline is a strategy that has been used to treat tobacco dependence and cessation on a population level in a number of states and by a number of health plans and businesses.

Q: What role will the quitline play in a comprehensive cessation program?

A: A national tobacco quitline network will provide universal access to evidence-based counseling and medications so that all smokers who want to quit can do so successfully.

Effective treatments for tobacco dependence exist. The extant literature speaks eloquently to the effectiveness of both proactive telephone counseling as well as pharmacotherapy for smoking cessation. However, the reach or use of such treatments remains low. Further, research has shown that there are significant disparities in access to evidence-based treatment across geographic locations, among certain racial and ethnic minorities, and across socioeconomic groups. Population-based strategies are essential to address disparities in access to treatment, in order to ensure that all tobacco users, regardless of where they live, can obtain treatment without barriers.

A proactive telephone quitline that provides both evidence-based counseling and medications is such an effective strategy because it has the capacity to be individualized to the particular characteristics of the caller, while at the same time provide the widest access possible to the full population of American smokers who want to quit.

Q: What is "proactive telephone counseling?"

A: In contrast to a typical helpline that only provides brief advice in response to incoming calls, proactive quitlines are characterized by two key components. First, when the smoker makes the first call, an extensive intake is completed, when all the critical information necessary to personalize an evidence-based quit plan is collected. Second, this extensive intake call is followed by a series of subsequent outgoing counseling calls, initiated by the quitline, to assist the smoker every step of the way as s/he works though the quit plan. The quitline is also equipped to receive additional incoming calls from smokers during a quit attempt – for example if a smoker trying to quit is having a day of particular difficult withdrawal symptoms, s/he can call the quitline and obtain individualized evidence-based advice. In essence, a proactive quitline is designed to serve as a real-time partner in successful quitting. Quitlines may also

work with healthcare providers and, after receiving permission from a tobacco user, contact that person directly for the first intake counseling session.

Q: You also mentioned the literature that supports the effectiveness of proactive telephone counseling for smoking cessation. Please tell the Court about that evidence.

A: There have been a number of research studies published, including research published in the *New England Journal of Medicine* and JAMA, that has documented the clinical effectiveness of proactive quitlines in helping smokers to quit. In addition, this recommendation is supported by two published meta-analyses. First, a meta-analysis published in the 2000 United States Public Health Service Clinical Practice Guideline *Treating Tobacco Use and Dependence,* demonstrated a 1.2 estimated odds ratio for proactive telephone counseling. A more recent meta-analysis published in 2002 by the Cochrane Collaborative involving 27 studies demonstrated a 1.56 odds ratio for proactive telephone counseling compared to less intensive intervention (e.g., self help quitting materials).

Q: You identified the Clinical Practice Guideline, *Treating Tobacco Use and Dependence*, as one of the documents that you rely on in support of the opinions you are offering the Court. You indicated that you chaired the panel that developed the 2000 Guideline, correct?

A: Yes, I did.

Q: Why have you elected to rely on the 2000 Guideline to support your opinions?

A: The recommendations and analyses contained in the 2000 Guideline provide the most comprehensive recommendations for treating tobacco use and dependence. In my view, any smoking cessation program should offer to smokers and promote the effective provision of the therapies and strategies contained in the Guideline, as reinforced by some of the subsequent

literature reviews that I also rely on for my opinions. So in this way, the recommendations in the 2000 Guideline form much of the structure of what will be, in my opinion, an effective cessation program.

Q: Why was the 2000 Guideline prepared?

A: The 2000 Guideline was developed to update the AHCPR's Smoking Cessation Clinical Practice Guideline No. 18, which was published in 1996 in response to new, effective clinical treatments for tobacco dependence identified since 1994 (the end date of the literature review for the 1996 Guideline), treatments that promised to enhance the rates of successful tobacco cessation.

Q: As background then, I'd like to start by asking you about the 1996 Guideline. You indicated that you chaired the AHCPR's Guideline panel that created the Smoking Cessation Clinical Practice Guideline No. 18, correct?

A: Yes, I did.

Q: To start, what is AHCPR?

A: AHCPR, now known as the Agency for Healthcare Research and Quality (AHRQ), is an arm of the Department of Health and Human Services. It is charged with helping to improve the quality, safety, efficiency, and effectiveness of healthcare in the United States. One of the things it has done is convene expert panels to develop clinical guidelines for health care practitioners.

Q: How did the idea to develop what became the 1996 Guideline come about?

A: The 1996 Guideline was developed because of the recognition that, although tobacco use is the chief avoidable cause of illness and death in the United States, responsible for over 400,000 deaths annually, physicians and other health care clinicians too often fail to assess and treat tobacco use consistently and effectively. This is the case despite the existence of effective,

preventive treatments for tobacco use.

Q: How did you come to be Chair of the panel responsible for developing the 1996 Guideline?

A: Sometime in the early to mid 1990s, I was contacted by AHCPR and asked if I would chair a federal panel to produce a clinical practice guideline for smoking cessation. The recruitment process was very formal. I was invited to a meeting held in Washington, where I was informed that AHCPR required that the Guideline be developed by following the most scientifically appropriate process. The idea was to take the extant literature – everything we knew at that point in time – and distill it in a way to help physicians to assist patients in quitting smoking.

Q: Who were the other panelists, and how was the panel selected?

A: AHCPR selected the other panelists, and I do not recall whether they asked me for recommendations or not. The panel for the 1996 Guideline was comprised of: William C. Bailey, Professor of Medicine and the Director of the Lung Health Center at the University of Alabama at Birmingham; Stuart J. Cohen, Professor in the Departments of Public Health Sciences and Internal Medicine and Director of the Health Services Research Center at the Bowman Gray School of Medicine in Winston-Salem, North Carolina; Sally Faith Dorfman, a gynecologist and public health consultant in Cornwall and New York, NY; Michael Goldstein, Assistant Psychiatrist-in-Chief at the Miriam Hospital and Associate Professor of Psychiatry and Human Behavior at the Brown University School of Medicine; Ellen Gritz, Professor and Chair of the Department of Behavioral Science at the University of Texas's M.D. Anderson Cancer Center; Richard Heyman, Chairman of the Committee on Substance Abuse at the American Academy of Pediatrics; John Holbrook, Professor of Medicine at the University of Utah School

of Medicine; Carlos Roberto Jaen, Assistant Professor of Family Medicine and Social and Preventive Medicine and Director of the Center for Urban Research in Primary Care at the State University of New York at Buffalo; Thomas E. Kottke, Professor in the Division of Cardiovascular Diseases at the Mayo Clinic and Foundation; Harry A. Lando, Professor, Division of Epidemiology at the University of Minnesota School of Public Health; Robert Mecklenburg, Dental Coordinator at the National Cancer Institute; Patricia Dolan Mullen, Professor and Deputy Director of the Center for Health Promotion and Research Development at the University of Texas School of Public Health; Louise M. Nett, Research Associate in the Clinical Research Division at the Center for Health Sciences Education in Denver; Lawrence Robinson, Deputy Health Commissioner of the Philadelphia Department of Public Health; Maxine L. Stitzer, Professor, Department of Psychiatry and Behavioral Sciences at Johns Hopkins/Bayview Medical Center; Anthony C. Tommasello, Director of the Office of Substance Abuse Studies at the University of Maryland at Baltimore School of Pharmacy; Louise Villego, Director of the Patient Education Office at the M.D. Anderson Cancer Center; and Mary Ellen Wewers, Associate Professor, Department of Adult Health and Illness Nursing in the College of Nursing at Ohio State University.

Q: Without going through the background of every panelist, what were the types of expertise and experience represented in the panel?

A: We had a large number of clinicians. We had specialists in substance abuse, in psychiatry and psychology, epidemiologists, and editors of Surgeon General's Reports (including Dr. Lando, who was one of the scientific editors of the 1988 Report on Nicotine Addiction and who has focused his research on primarily on the development of effective multicomponent behavioral programs for smoking cessation).

Q: Please describe the process by which the 1996 Guideline was developed.

A: AHCPR directed the panel to identify effective, experimentally validated smoking cessation treatments and practices. We developed the 1996 Guideline to meet this direction over approximately a two year period. To begin, the panel undertook a systematic review of the available scientific literature – this was a comprehensive examination of literature published from 1976 through 1994. We employed a variety of search strategies in an attempt to pull every article in English language journals, and a total of approximately 3000 articles were reviewed by a staff of scientists and support individuals with the guideline panel.

Q: Once the literature review was completed, how did the panel evaluate it for purposes of arriving at recommendations in the 1996 Guideline?

A: The panel followed a defined, rigorous process for how to review and interpret the data contained in the literature. The appropriateness of an article was determined by applying the criteria for inclusion that had been established by the panel. The criteria were that the article (a) reported the results of a randomized, controlled trial of a tobacco-use cessation intervention, (b) provided follow-up results at least five months after the quit date, (c) was published in a peer-reviewed journal, (d) was published between 1975 and 1994, and (e) was published in English. In addition, published, peer-reviewed randomized controlled trials were considered to provide the strongest evidence in support of guideline recommendations. This decision was based on the judgment that randomized controlled trials are the clearest scientific method for judging comparative efficacy. The panel made this decision recognizing the limitations of randomized controlled trials, particularly considerations of generalizability with respect to patient selection and treatment quality. In some cases, panel conclusions were based partly on the results of previously published meta-analyses. Published meta-analyses were used when they (a)

synthesized data from related sets of randomized clinical trials of smoking cessation methods, (b) were published in peer-reviewed journals, (c) were published between 1975 and 1994, and (d) were published in English.

In addition to this review of randomized controlled trials and meta-analyses as the basis for making recommendations, the panel occasionally made recommendations in the absence of randomized controlled trials. It did so when faced with an important clinical practice issue for which considerable suggestive evidence existed. The panel clearly identified the level or strength of evidence that served as the basis for each of its recommendations.

Q: Did the panel do anything other than review the published literature in developing the 1996 Guideline?

A: Yes, we did. We held an open forum in Washington, DC, in November 1994. The meeting had been publicized in the Federal Register. A range of healthcare providers, professional groups, and even individuals provided input and testimony. We considered this input and testimony as part of the preparation process.

Q: Was the 1996 Guideline peer-reviewed?

A: It was. We invited outside reviewers to review the guideline draft, and AHCPR placed a notice in the Federal Register inviting individuals to review and comment on the draft Guideline. A total of 71 reviewers provided comments, including clinicians, health care program directors, social workers, counselors, health educators, researchers with clinical experience, consumers, and key personnel at federal agencies like CDC, NIDA, NCI, and FDA. We evaluated and considered all of the comments received, which generally assessed the draft Guideline on the basis of five criteria: validity, reliability, clarity, clinical applicability, and utility. The Guideline was not published until after all the peer-review comments were considered and the Guideline

went through a clearance process with AHCPR.

Q: What were the basic clinical recommendations in the 1996 Guidelines?

A: We provided the overriding message of the Guidelines in its Executive Summary: "Smoking cessation interventions offer clinicians and health care providers their greatest opportunity to improve the current and future health of all Americans." We concluded that the guideline offered "a simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome this powerful addiction."

There were six major recommendations made: (1) effective smoking cessation treatments are available, and every patient who smokes should be offered one or more of these treatments; (2) it is essential that clinicians determine and document the tobacco-use status of every patient treated in a health care setting; (3) brief cessation treatments are effective, and at least a minimal intervention should be provided to every patient who uses tobacco; (4) a dose-response relation exists between the intensity and duration of a treatment and its effectiveness, and in general, the more intense the treatment, the more effective it is in producing long-term abstinence from tobacco; (5) three treatment elements, in particular, are effective – nicotine replacement therapy, social support and skills training/problem solving assistance – and one or more of the three should be included in smoking cessation treatment; and (6) effective reduction of tobacco use requires that health care systems make institutional changes that result in systematic identification of, and intervention with, all tobacco users at every visit.

Q: Returning to the 2000 Guideline, why was an update to the 1996 Guideline undertaken?

A: The accelerating pace of tobacco research that prompted the update is reflected by the

fact that 3,000 additional articles were published between 1995 and 1999 and contributed to the updated guideline. For the 2000 Guideline, the review included a total of 6,000 articles – again, this was an attempt to review every article that had ever been published on the subject of tobacco cessation in an English language journal.

Q: What were the major areas that were updated in the 2000 Guideline?

A: The most important updates focused on three areas. First, the updated guideline contains even stronger evidence of the association between counseling intensity and successful treatment outcomes, and also included evidence of additional effective counseling strategies, including telephone quitline counseling and counseling that helps smokers enlist support outside the treatment context.

Second, the updated guideline includes more pharmacologic treatment strategies than were identified in the previous guideline, because by 2000, there were five different smoking cessation medications that had been proven to be effective and additional information was available showing the effectiveness of combinations of nicotine replacement therapies and pharmacotherapies that are obtained over-the-counter;

Third, additional evidence was available on the cost-effectiveness of counseling and pharmacotherapy relative to other routinely reimbursed medical interventions such as treatment of hyperlipidemia and mammography screening.

Q: Did the same panel that had prepared the 1996 Guideline also develop the 2000 Guideline?

A: Yes, with one exception. Dr. Holbrook was not able to participate in the work undertaken for the 2000 Guideline. One other difference was the fact that the updated guideline was sponsored not just by AHRQ, but by a consortium of seven Federal Government and

nonprofit organizations: AHRQ; CDC; NCI; National Heart, Lung, and Blood Institute (NHLBI); NIDA; the Robert Wood Johnson Foundation; and UW-CTRI. The updated guideline was published by the U.S. Public Health Service.

Q: Was the process by which the panel developed the 2000 Guideline the same as that it had used for the 1996 Guideline?

A: Yes. We set out *a priori* levels of evidence, rating them as A, B and C. Every recommendation that the panel made therefore bears a strength-of-evidence rating that indicates the quality and quantity of the empirical support for the recommendation. An "A" rating indicates that multiple and well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings. A rating of "B" was given where some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. Ratings of "C" were reserved for important clinical situations where we as a panel achieved consensus on the recommendation in the absence of relevant randomized clinical trials.

We also undertook approximately between 20 and 25 meta-analyses, which were performed by Dr. Vic Hasselblad, a statistical methodologist at Duke University. Our analysis included all of the studies that have looked at the particular types of counseling and examined particular treatments, in order to generate odds ratios compared to absence of treatments.

In order to make recommendations, the panel looked to the number of studies, number of participants, consistency, and sum weight of the evidence, as well as the experience of panel members.

Q: Can you provide an example of a C level recommendation?

A: Yes, I can. One of the issues we confronted was the need to address helping adolescent

smokers quit, but there were limited studies on this topic at the time and the panel had to make decisions as to what to recommend that physicians tell teens to help them quit. We took a conservative approach and concluded that it is appropriate to use counseling methods for adolescents that had been identified as effective for adults.

Q: What was the peer-review process for the 2000 Guideline?

A: Panel and consortium members invited 175 outside reviewers to review the updated guideline. A total of 70 provided comments, so the peer-review process was far more expansive than what is typically used for a journal article (typically about three peer reviews).

Q: Has the 2000 Guideline been widely distributed?

A: It has. Almost five million copies of the Guideline and its products have been distributed nationally to physicians and health professionals.

Q: How do you assess the impact of the 1996 and 2000 Guidelines?

A: We think they have had a substantial measurable impact. More clinicians today are addressing tobacco use with their patients and providing evidence based treatments than ever before. And we know that when a clinician addresses tobacco use, their patients are more likely to quit. The Guidelines have also been one of the most extensively cited tobacco control publications. For example, the most commonly used independent assessment of scientific citations, the Institute for Scientific Information (ISI), reports more than 650 citations of the 2000 Guideline in other scientific publications since it was published in June 2000.

Q: You mentioned that literature reviews undertaken after publication of the 2000 Guideline have also looked at the effectiveness of practice telephone counseling. Can you provide an example of such a review for the Court?

A: I can. In 2003, a Cochrane Review of 27 trials of telephone counseling for smoking

cessation, using criteria of at least six months abstinence, concluded that proactive telephone counseling is effective and particularly successful when multiple phone contacts take place at the time of a quit attempt. This review was published as Stead LF, Lancaster T, Perera R. Telephone counselling for smoking cessation, Cochrane Database Syst Rev. 2003; (1):CD002850 (U.S. Exhibit 89,465). The reviewers noted that counselor calls are "likely to increase the chances of quitting relatively by around 50 percent or absolutely by two to four percentage points compared to a minimal intervention such as providing standard self-help materials." Other Cochrane reviews provide the opportunity to conduct detailed comparison the effectiveness of proactive telephone counseling to self-help materials and group sessions, in particular Lancaster T, Stead LF. Self-help interventions for smoking cessation, Cochrane Database Syst Rev. 2002; (3):CD001118 (U.S. Exhibit 89,466); and Stead LF, Lancaster T. Group behaviour therapy programmes for smoking cessation, Cochrane Database Syst Rev. 2002; (3):CD001007 (U.S. Exhibit 89,467).

Q: You also indicated that you believe it is important that quitlines eliminate barriers to accessing treatment. What are these barriers, and why are they a concern?

A: There are a number of barriers, the most important of which I mentioned previously: eligibility requirements, screening processes, co-payment obligations, language and other cultural barriers, limited access to services, lack of awareness, limits to covered benefits, and fragmentation of care. They are an extraordinary concern, because they prevent a majority of persons from accessing treatment that has proven to be effective at helping people to quit smoking.

Q: On what do you base your opinion that barriers to access have prevented smokers from utilizing effective smoking cessation treatment?

A: My opinion is based on real-world experience with state and local smoking cessation quitlines. As of mid-2004, there were 36 state-managed quitlines, five states with formal agreements for coverage by the Cancer Information Service at the National Cancer Institute, one state that receives services from the American Legacy Foundation, and eight states and DC with no quitline services. But these state quitlines are generally not available to all smokers, are only available for part of the day, are not promoted, do not universally offer medications to all callers, do not meet language and cultural needs of large numbers of smokers, and do not offer a complete menu of services to smokers. The existence of these barriers to effective treatment means that only 1-2% of smokers use state quitlines in a given year. This is identical to the experience we have in Wisconsin, where we do not have sufficient financial resources to offer medications or engage in quitline promotion – in fact, we were recently forced to cut our limited media promotion because when this limited promotion was initiated, the response was so great that we did not have the funds to pay for the call volume. Most smokers want to quit – more than 70% in most surveys – and almost 40% of smokers attempt to quit every year. Wisconsin is no exception and if adequately promoted and provided in a barrier-free environment, many more smokers would utilize the counseling and medications of a quitline.

The issue of barriers was one of the critical things that the Cessation Subcommittee recognized in its work. A theme throughout our deliberations was the importance of providing evidence-based treatments particularly to the members of our society who have the least opportunity to access them.

Q: Is it your recommendation that a national telephone quitline replace existing state quitlines?

A: No. States should have the capacity to maintain their own quitlines and personalize that

quitline to the state. What I'm recommending is that a national quitline network be funded so that all American smokers who want to quit can get access to telephone counseling and medications and that we build up on the state and regional network to ensure that local control can be maintained and built upon. Clearly there are state- and region-specific needs, and there are state and regional services that are best able to serve local populations. For this reason, I feel, and the Subcommittee felt incredibly strongly, that local control should be maintained but maintained in the context of a nationally funded system that delineates the core performance standards that will result in maximum reach and maximum effectiveness.

B. Medications to Assist Tobacco Cessation

Q: Dr. Fiore, I want to ask now about medication to treat tobacco dependence. You stated earlier that the national quitline network should have the capacity to provide callers with universal access to smoking cessation medications. What are the medications to which you are referring?

A: FDA has approved six medications for smoking cessation. Five of these medications are nicotine replacement therapies – the nicotine gum, the nicotine patch, the nicotine lozenge, the nicotine inhaler, and the nicotine nasal spray. The sixth medication, bupropion SR, is an antidepressant that has been shown to be effective in treating tobacco dependence, presumably because of it capacity to block the re-uptake of dopamine and norepinephrine in the brain and nervous system. It has also been shown to relieve depressed mood. The nicotine gum and nicotine lozenge are available exclusively over-the-counter. The nicotine patch is also available over-the-counter, though a generic nicotine patch may be prescribed by a physician. The nicotine inhaler, nicotine nasal spray, and bupropion SR are only available by prescription.

Q: How would the quitline dispense approved pharmacotherapies?

A: Based on information in the FDA-approved package inserts, a trained quitline counselor will discuss with the smoker which medicine may be most appropriate, based on prior experience with the medicines, contraindications, patient preference and other factors as defined in the 2000 Guideline. If an over-the-counter medication is most appropriate, the medication will be sent directly to the smoker in the mail along with other personalized quitting information. If it was determined that the most appropriate medicine for the smoker was a prescription agent such as bupropion, when the quitline mails other quitting information to the patient, it would include a voucher for the prescription medication. At that point the smoker would have to visit a physician or other provider who would review the appropriateness of the medicine, sign the prescription, and allow the patient to get the voucher filled by a pharmacy.

Q: Isn't that a barrier to access?

A: If the caller did not have a regular physician, then yes, it would be a barrier. But for about 70% of smokers, it is anticipated that over-the-counter medications will be most appropriate for them and that medicine will be mailed directly to them. In addition, if the absence of a physician was identified as a barrier for a smoker, then the quitline counselor would not recommend prescription medications.

Q: Are there quitlines that have done this successfully in the past?

A: Yes, some quitlines have dispensed pharmacotherapies. For example, Minnesota has contracted to dispense over the counter medications with its quitline counseling, as has the State of Maine.

In Wisconsin, in a program that targeted older smokers, we dispensed nicotine patches through the mail when smokers called the quitline. The demand for this program was extraordinary. We offered nicotine patches to smokers over 65 who called the state quitline for a

six month period (a limited budget allowed us to run the program for only six months). With a series of news conferences as the only promotion, 5.5 percent of the population of senior smokers in the state called the quitline during these six months while nicotine replacement therapy was being offered.

Q: Are the smoking cessation medications that are available effective?

A: Yes.

Q: What is the evidence supporting the effectiveness of smoking cessation medications?

A: The effectiveness of these medications has been reported in the scientific literature. Based on the meta-analyses conducted by the 2000 Guideline Panel, the Clinical Practice Guideline recommended bupropion SR, the nicotine gum, the nicotine patch, the nicotine nasal spray, and the nicotine inhaler as efficacious first-line smoking cessation treatments that smokers should be encouraged to use. As the 2000 Guideline reported, odds ratios and estimated abstinence rates for each medication compared to placebo are listed below. These results are based upon comprehensive meta-analyses of published clinical trial data on the medications up to the time of the publication of the Guideline:

Pharmacotherapy	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
Placebo	1.0	17.3
Bupropion SR	2.1 (1.5, 3.0)	30.5 (23.2, 37.8)

Pharmacotherapy	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
Placebo	1.0	17.1
Nicotine gum (2 mg)	1.5 (1.3, 1.8)	23.7 (20.6, 26.7)

Pharmacotherapy	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
Placebo	1.0	10.5
Nicotine inhaler	2.5 (1.7,3.6)	22.8 (16.4, 29.2)

Pharmacotherapy	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence Rate (95% C.I.)
Placebo	1.0	13.9
Nicotine nasal spray	2.7 (1.8, 4.1)	30.5 (21.8, 39.2)

Pharmacotherapy	Estimated Odds Ratio (95% C.I.)	Estimated Abstinence (95% C.I.)
Placebo	1.0	10.0
Nicotine patch	1.9 (1.7, 2.2)	17.7 (16.0, 19.5)

Q: Please explain, using the nicotine patch as an example, what the different numbers mean for the information you have provided for the approved cessation pharmacotherapies.

A: The chart compares the efficacy of the nicotine patch to a placebo patch – one that looks similar but is inert. The meta-analysis was based on 27 separate studies. The "Estimated Odds Ratio," provides the ratio of long-term abstinence among the study groups that got the nicotine patch versus a placebo. The chart shows that, taken together, people getting the nicotine patch were about 1.9 times – 90% – more likely to achieve long-term abstinence than the people in the studies who received a placebo patch. The parenthetical shows the statistical range (the 95% confidence interval) for this meta-analysis of 27 studies. This statistical range allows us to state

that with 95% certainty, long-term abstinence (successful smoking cessation) with the nicotine patch ranged from 1.7 (70%) to 2.2 (120%) times more likely than with the placebo patch.

The column on the right shows the quantitative estimated quit rate for users of the placebo and nicotine patches. About 10% of people who got the placebo patch quit, while 17.7% (ranging from 16.0% to 19.5%) of people in the studies who got the nicotine patch quit. Importantly, both those who received the active patch as well as the placebo patch received counseling. That, in large part, contributes to the 10% success rate among placebo patch users.

Q: What is the significance of expressing the outcome as an odds ratio as opposed to looking at the percentage of study participants who remain abstinent after a specified period of time?

A: An odds ratio gives you a relative measure of the effectiveness of the treatment that takes into account differences between the populations of smokers treated, the intensity of the counseling condition, and other factors that might either increase or decrease the absolute quit rates. So, for example, if one is concerned that participants in a smoking cessation study are already motivated to quit, based on the fact that they have agreed to participate, the result might be a higher absolute quit rate in both the control (or placebo) group and the group receiving therapy. Even under these conditions, the *relative* effectiveness of the treatments – the odds ratio – will be maintained. Thus, odds ratios protect against a result being skewed by self-selection, adjuvant counseling, etc.

Q: Are there currently any approved cessation medications other than those reviewed in the 2000 Guideline?

A: Yes. Since the PHS Clinical Practice Guideline was issued, FDA has approved a nicotine lozenge. Since it had not yet been approved at the time the Guideline was published, the 2000

Guideline did not make a recommendation regarding its use.

Q: What other evidence exists as to the effectiveness of pharmacotherapies to aid smoking cessation?

A: The Cochrane Collaborative has also published systematic reviews of the scientific evidence regarding smoking cessation medications.

In 2004, a review article on nicotine replacement therapy for smoking cessation was published as Silagy C, Lancaster T, Stead L, Mant D, Fowler G. Nicotine replacement therapy for smoking cessation, Cochrane Database Syst Rev. 2004; (3):CD000146 (U.S. Exhibit 89,468). The authors reviewed the extant literature on the nicotine gum, the nicotine patch, the nicotine nasal spray, the nicotine inhaler, and the nicotine lozenge. They found that persons who used nicotine replacement therapy had significantly higher abstinence rates than persons who either received placebo or no nicotine replacement therapy (odds ratio 1.77, 95% confidence interval 1.66-1.88). The odds ratios and 95% confidence intervals for the different forms of nicotine replacement therapy were:

Pharmacotherapy	Odds Ratio (95% C.I.)
Nicotine gum	1.66 (1.52, 1.81)
Nicotine patch	1.81 (1.63, 2.02)
Nicotine nasal spray	2.35 (1.63, 3.38)
Nicotine inhaler	2.14 (1.44, 3.18)
Nicotine lozenge	2.05 (1.62, 2.59)

The authors concluded that all of the commercially available forms of nicotine replacement therapy are effective and increase the odds of quitting approximately 1.5 to 2 fold, a

finding very consistent with the findings in the 2000 Guideline.

In 2003, the Cochrane Collaborative also published a review of antidepressants for smoking cessation, which is cited as Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation, Cochrane Database Syst Rev. 2003;(2):CD000031 (U.S. Exhibit 89,469). The authors reviewed the extant literature on many antidepressants that have been tested to ascertain whether they aid in long-term smoking cessation, finding that only two medications – bupropion and nortriptyline – were effective for smoking cessation and that both doubled the odds of cessation. The odds ratios and 95% confidence intervals for these two medications are presented below.

Pharmacotherapy	Odds Ratio (95% C.I.)
Bupropion	2.06 (1.77, 2.40)
Nortriptyline	2.79 (1.70, 4.59)

It should be noted that the 2000 Guideline panel reviewed the evidence surrounding nortriptyline and recommended it as a second-line medication for smoking cessation. At the time of the preparation of the 2000 Guideline and the Cochrane Review, nortriptyline had not been evaluated by or approved by the FDA for smoking cessation. It is infrequently used for smoking cessation because it is a medication with many side effects and some safety concerns.

Q: Does the ability for a quitline to provide FDA-approved medications as part of its services affect whether smokers utilize the quitline services?

A: Very much so. Utilization rates increase dramatically when nicotine replacement therapies are added to the range of treatments offered by a quitline. In Minnesota, for example, utilization rates jumped from 1-2% of smokers to about 6% of smokers when the state quitline

was expanded to include provision of pharmacotherapies.

Q: Are quitlines a cost-effective method of treatment?

A: Yes.

Q: Why?

A: Quitlines can provide evidence-based cessation treatment to very large numbers of smokers without barriers and without the much greater costs of in-person medical care. They are highly acceptable and accessible to a wide range of smokers, including the elderly, rural residents, certain racial and ethnic minorities, and the uninsured. These populations often smoke at the highest rates and don't have easy access to in-person medical care. In contrast, more than 95% of adult United States residents have access to a telephone.

Q: What is the estimated cost for a national quitline network?

A: The annual cost estimate for a national tobacco quitline network is $3.2 billion. This dollar figure includes costs associated with: providing funding to states to expand existing quitlines or develop new quitlines, with all quitlines ultimately meeting national core performance and accountability standards; free access to services for all callers (with no co-payments required, and services offered to all smokers rather than just to specific populations such as pregnant women); counseling services that include at least four person-to-person proactive telephone calls from the quitline; provision of free FDA-approved pharmacotherapy for every caller for whom it is medically appropriate (either over-the-counter medications for nicotine replacement therapies or vouchers for prescription medications such as bupropion that must be signed by a physician); and a nationwide toll-free number that is accessible 24 hours per day, 7 days per week.

Q: Where does the cost estimate come from?

A: The cost estimate is derived from the information submitted to the Cessation Subcommittee by leading providers in the field of quitline services. Group Health Cooperative of Puget Sound, now known as Free & Clear, Inc., has been for many years the largest provider of quitline services in the United States, currently serving eight states with a combined population of over 30 million who receive varying degrees of quitline services. For example, for the states that are currently served by Free & Clear, services are usually limited (counseling only, limited hours and often extensive eligibility requirements). For members of the Group Health Cooperative, a managed care organization that provides the quitline to its enrollees, services are more significant, although offered with varying degrees of coverage and co-payments, as detailed by Susan Curry in the *New England Journal of Medicine* in 1998 (Curry SJ, Grothaus LC, McAfee T, Pabiniak C. Use and cost effectiveness of smoking-cessation services under four insurance plans in a health maintenance organization, N Engl J Med 1998; 339(10):673-9 (U.S. Exhibit 64,387). The Subcommittee relied on Group Health's cost determinations as evidence, because it has the extensive real-world experience in securing contracts with, and providing its services to, both public and private sector entities and to tens of millions of Americans.

Q: Did the Subcommittee simply take the Group Health written testimony and cost spreadsheet, which has been marked as U.S. Exhibit 89,470, and adopt it as the Subcommittee's cost recommendation?

A: No. The Subcommittee reviewed the Group Health data and testimony in great detail, and the spreadsheet that they provided generated an incredible amount of discussion and input from the Subcommittee membership that included Dr. Howard Koh, Commissioner of Health who directed the Massachusetts tobacco control program and had significant experience with statewide cessation services and Dr. Dennis Richling, who had developed smoking cessation

services and programs in the large company where he worked. Dr. Shu-Hong Zhu, who has published on quitlines in the *New England Journal of Medicine* and runs the California quitline program, provided expert testimony to the Subcommittee. Moreover, I had experience directing the Wisconsin tobacco quit line since 2000. So the entire Subcommittee reviewed the Group Health submission in great detail, calling on our extensive personal experience, as well as looking at it in the context of published research and expert testimony.

Q: Is the $3.2 billion annual cost based on an expected utilization rate?

A: Yes, it is. The expected call rate is 16% of smokers, with a total of 10% undergoing both counseling and medications. We were able to look to the Group Health experience that among callers to a quitline, approximately 85% choose to undergo some level of counseling, either single or multi-session, and of that group, use of medications is appropriate for 75%, and that is how we arrive at the 10% use figure.

Q: In your expert opinion, is 16% a realistic rate?

A: Yes, it is.

Q: Please explain why 16% is a realistic rate.

A: There are a number of reasons. First, the 16% expected call rate is based on use of the comprehensive quitline in Group Health Cooperative. Group Health achieved an 8% call rate for five consecutive years with essentially no promotional activity. Based on their experience in the provision of quitline services, they felt that 16% was an achievable call rate with the addition of a multicomponent promotional campaign. There is a variety of experience that we have in America that when you promote quitlines – when you pair a quitline to advertising and other promotional activities – rates of use are increased dramatically. And it was the consensus of the Cessation Subcommittee, after discussion and evaluation, that a 16% call rate, with 10%

utilization of services, was an appropriate expectation. In reaching this conclusion, we drew on the extraordinary expertise and real-world experience of the Subcommittee members as well as the experts that provided testimony. This included, again, both Subcommittee members like Dr. Howard Koh, experts who provided testimony like Dr. Shu-Hong Zhu, as well as Dr. Cheryl Healton, with her experience running the truth campaign for the American Legacy Foundation, and my personal experiences directing the Wisconsin tobacco quit line. In the case of Wisconsin, a promotional campaign based on very limited advertising dollars resulted in such high call rates that we had to stop the advertising because our projections indicated that we wouldn't have enough funding to pay for the quitline through the end of the year. The Subcommittee also had the experience of former Surgeon General David Satcher, who has extensive experience in health promotion. There is also fairly extensive peer-reviewed literature looking at use rates and media campaigns, such as some of the work of Dr. David Burns in NCI's Tobacco Control Monograph series. With all of this experience, literature, and testimony, the Cessation Subcommittee gave this issue very deliberate attention.

C. Sustained Multifaceted Media Campaign

Q: This is a good time to focus questions on the second component of a national comprehensive cessation program that you identified, an extensive paid media campaign to encourage Americans to quit using tobacco. Please describe what you mean by "an extensive paid media campaign."

A: A multifaceted media communications campaign is necessary to alert smokers to the existence and availability of the other services and components of the cessation program. Most fundamentally, if people do not know about the quitline or other available cessation services such as those provided by their clinicians, they will not be able to use them to help quit.

I recommend a comprehensive media campaign such as that described by the Cessation Subcommittee that includes four goals: first, to promote the use of the national tobacco quitline and other effective cessation interventions: second, to motivate tobacco users to make a quit attempt and increase demand for effective cessation services; third, to motivate parents to quit by informing them of the health risks that secondhand smoke poses to their families and informing them that their smoking increases the likelihood that their children will smoke; and fourth, to reach all segments of the population, including the most underserved and hard-to-reach populations such as low socioeconomic status, certain racial and ethnic minorities, and those of limited English proficiency.

Q: What are important characteristics for an extensive paid media campaign to have?

A: The promotional campaign needs to be guided by media and communications science as to the most effective messages and strategies to implement. It needs to be pervasive – that is, to be a consistent presence in the everyday lives of smokers in the same way smokers encounter tobacco marketing. To do that, the media campaign must use the full range of media – radio, television, print media, signage, Internet, etc.

Q: Should the annual budget for a media campaign be divided in any specific way between the four purposes that you have identified?

A: Not specifically. The Subcommittee wanted the Action Plan to have a series of characteristics that included powerful and effective messages that would be guided by media and communication science, that it be multifaceted and persuasive. But in terms of the allocation among those characteristics the Subcommittee felt, and I agree, that a standing group of communications experts would be best equipped to design it, evaluate it, and ensure that it was having the effectiveness intended.

Q: Are sustained media campaigns effective in contributing to cessation?

A: Yes. There is a substantial and consistent body of evidence that media campaigns, especially when they are integrated with other tobacco control actions, reduce the consumption of tobacco and the prevalence of tobacco use. Research on statewide tobacco control programs has shown that aggressive media campaigns have been effective in targeted ways such as prompting individuals to use evidence-based treatments such as quitline services, or discouraging children and adolescents from starting to smoke.

Q: What is some of that evidence?

A: The strongest evidence of effectiveness of such media campaigns comes from settings where they were implemented in the context of multicomponent programs. Such programs increased cessation across a variety of populations, indicating their widespread impact. This research was summarized by the CDC in 1999 as part of its publication, Best Practices for Comprehensive Tobacco Control Programs, cited in my expert report.

Q: What is the estimated annual cost for an extensive paid media campaign?

A: The annual cost estimate for an independent, comprehensive paid media campaign to accomplish its objectives and to reach all segments of society, including hard-to-reach populations, is $1 billion. This number was something that the Cessation Subcommittee arrived at as a consensus after careful consideration.

Q: Dr. Fiore, do you have experience with media campaigns?

A: I do. My work both in Wisconsin and nationally has given me experience with media campaigns related to health prevention and disease prevention, particularly in the area of tobacco control.

Q: Did any of the other members of the Cessation Subcommittee bring media

experience to the subcommittee deliberations?

A: Yes. There was extensive media experience on the panel. Dr. Robert Croyle has been involved with the cancer control and population science media activities as part of his portfolio of work at the National Cancer Institute. Dr. Susan Curry, both in her previous work at Group Health Cooperative of Puget Sound and the University of Washington as well as in her current role at the University of Illinois in Chicago, has media and communications activities as a component of many of her programs. Ron Davis, another member of the Subcommittee, has had a variety of roles, including serving as a director of the United States Office on Smoking and Health, serving as the Chief Medical Officer for the State of Michigan, where he played an active role in communicating messages of importance for health promotion and disease prevention to the residents of Michigan. Currently in his role as director of the Center for Health Promotion and disease prevention at the Henry Ford Health Systems, Dr. Davis is promoting and developing programs that improve health among the enrollees of the Henry Ford Health System. The Center for Medicare and Medicaid Services, where Kathryn Gordon works, has been involved actively in a program to test a new smoking cessation benefit among Medicare enrollees. As I mentioned earlier, Cheryl Healton has as part of her core portfolio of activities extensive media activities, including the highly effective "Truth Campaign" directed by the Legacy Foundation. Rosemarie Henson, who directs the United States Office on Smoking and Health, is involved in extensive activities aimed at helping keep kids from starting to smoke and helping adults to quit. I previously mentioned Howard Koh, a physician who directed the comprehensive tobacco control program in Massachusetts in his role as its Commissioner of Health. Jim Marks, who is now at the Robert Wood Johnson Foundation, at the time of the Subcommittee had an extensive amount of media experience that was essential in his role as

Director of the CDC National Center for Chronic Disease Prevention and Health Promotion. Tracy Orleans, at the Robert Wood Johnson Foundation, has directed a number of programs on tobacco and has promoted the programs in order to increase utilization. David Satcher in his role as Surgeon General of the United States directed communications activities at the United States Public Health Service including a number of health promotion and disease prevention communications initiatives. And John Seffrin, Chief Executive Officer of the American Cancer Society, led the ACS's communications efforts to prevent cancer in America including its communications efforts to reduce tobacco use.

Q: What did the Subcommittee consider in arriving at its $1 billion recommendation?

A: A number of considerations were made by the Subcommittee in coming up with this number. The first was the nation's collective experience between 1967 and 1970, when the Federal Communications Commission required licensees who broadcast cigarette commercials to provide free media time for anti-smoking public service announcements under the Fairness Doctrine. The time donated for the anti-smoking messages amounted to approximately $307 million per year in 1997 dollars. In addition, there has been experience with other media campaigns at the state and national level. One example is the American Legacy Foundation's "Truth Campaign," which was a much more limited that the one proposed as part of the National Action Plan. And lastly in terms of these big picture factors that went into the analysis by the Subcommittee, there was the recognition that a comprehensive media counter force was needed to counter the ten to twelve billion dollars per year that the tobacco industry currently spends on advertising and promotion. And we reached the conclusion that a counter weight to that of approximately 10 percent was a reasonable one to have an impact above and beyond the

powerful media noise that smokers and nonsmokers are exposed to as a result of the tobacco industry advertising and promotion.

Q: Some of the testimony that the Subcommittee received suggested that a national television campaign could be created for $100 million per year or less, correct?

A: Yes.

Q: Given that testimony, why did the Subcommittee recommend a $1 billion annual marketing expenditure?

A: Some have suggested that it would cost approximately $100 million dollars to mount a television-only campaign. Others have estimated based on experience with the Fairness Doctrine in the early 1970s that even just a television campaign would cost much more. The Subcommittee on Cessation didn't envision just a television campaign. Rather, it called for a comprehensive, multifaceted media campaign that would have the four very broad goals described above (promote the Quitline, motivate smokers to try to quit, motivate parents who smoke, reach underserved and hard-to-reach populations). Moreover, the proposed comprehensive media campaign would have as additional goals encouraging smokers to see their clinicians who would be better trained to treat them as a result of the National Action Plan and may access new counseling and medications that will be discovered over time as a result of the research funded through the National Action Plan. The collective, real world experience and communications expertise of the Subcommittee on Cessation concluded that this comprehensive multifaceted campaign would cost $1 billion.

D. Broad and Balanced Research Agenda

Q: Turning to the next component of the national cessation program you identified, why are you recommending a new, broad, and balanced research agenda to achieve future

improvements in the reach, effectiveness and adoption of tobacco dependence interventions across both individuals and populations?

A: It is vital that we implement a research agenda that provides for basic, clinical, public health, translational, and dissemination research in order to improve our tobacco control efforts.

Q: You use the terms "basic," "clinical," "public health," "translational," and "dissemination" to describe the research. What do you mean by those terms?

A: Basic research refers primarily to laboratory and bench research aimed at developing new and effective counseling and medications designed to treat smokers and help them quit. For example, it might investigate some genetic factors that may translate into greater difficulty in quitting. Clinical research refers to research that involves patients and often evaluates the safety and effectiveness of medications and counseling to help smokers quit.

Public health research refers to the broader study of tobacco dependence treatments taking a population-wide approach. One such example is communications science interventions that lead specific segments of the population, such as different racial, ethnic, educational, and socioeconomic groups to try to quit.

Translational research involves evaluating strategies that are designed to deliver findings from the laboratory to the patient, often involving scientists from a number of different disciplines who work together.

Finally, dissemination research refers to studies that evaluate the impact of strategies that are designed to ensure that smokers or their clinicians use the research findings that were discovered.

Q: Does such a multidimensional research plan require oversight and coordination?

A: Yes.

Q: Who should perform that role, and what would that entail?

A: One model is the Flight Attendant Medical Research Institute (FAMRI) research fund, which was set up in the settlement of tobacco litigation in Florida. In that instance, a Scientific Advisory Board guides FAMRI administratively through an identification of key scientific questions that need to be answered and a process to independently peer review the applications of scientists who propose to answer those questions. Such a model might be used to oversee the research activities of the National Action Plan. Of course, the NIH provides a wonderful model of how to run a large peer-reviewed research enterprise.

Q: Why are the types of research you have identified as important to include in a comprehensive cessation program?

A: The Subcommittee on Cessation identified two core needs for tobacco cessation research and I endorse those two key questions. We need to identify tobacco dependence treatments that first are effective in reducing the disparities in tobacco use and second, that increase long term successful cessation rates to at least 50%.

Such a broad and balanced set of research initiatives is important to improve treatments for tobacco dependence and train the next generation of tobacco scientists. Current treatments for tobacco dependence, while significantly more effective than quitting on your own, still result in only 10% to 30% of smokers achieving long-term success. When viewed from a medical perspective, these quit rates are comparable or superior to the effectiveness of treatments for other chronic diseases. By that, I mean the following - as a doctor, I would love to have a first-line, safe, relatively inexpensive treatment for my patients with hypertension that results in 30% of those patients entering into longterm remission after just three months on the medication.

Moreover, substantial declines in national smoking rates is difficult to achieve at present

because certain populations either are not aided by current treatments, or are not adequately exposed to them. Populations that currently are less likely to benefit from available treatments include those with psychiatric co-morbidities such as depression, pregnant women, certain racial and ethnic minorities, adolescent smokers, and individuals with very high levels of nicotine dependence.

My belief is that a well-funded, sustained research effort could develop interventions that produce long term success in 50% of smokers treated in a given quit attempt and will be effective in eliminating the disparities in tobacco use that exist today.

Q: Do you refer to smoking as a "chronic disease?"

A: Yes.

Q: Why?

A: Tobacco dependence shows many features of a chronic disease. As with other chronic diseases such as hypertension, hyperlipidemia, and diabetes, patients who smoke often cycle through multiple periods of relapse and remission. Moreover, a failure to appreciate the chronic disease nature of tobacco dependence may undercut clinicians' motivation to treat tobacco use consistently, instead viewing the smoker or the clinician as a failure. Finally, recognizing the chronic disease nature of tobacco dependence places the treatment of tobacco dependence squarely within the scope of responsibilities of primary care clinicians.

Q: What will the annual cost of the research program be?

A: The annual cost estimate for a new, broad, and balanced research agenda is $500 million. At that funding level, such a research agenda would permit the development of interventions to dramatically increase smoking cessation rates and to identify treatments for under-served tobacco users, including adolescents, racial and ethnic minorities, pregnant smokers, highly

addicted smokers, and those with other addictions or psychiatric co-morbidities. The research agenda cost was the consensus opinion of the Cessation Subcommittee.

Q: What is the $500 million recommendation based on?

A: The genesis for this is the recognition the two key factors are missing as we currently attempt to help more Americans to quit successfully. The first is that our success rates, while impressive from a chronic disease perspective, in fact are still less than 50 percent, in some instances 15, 20, or 30 percent. And it was felt that we have to come up with research that would get quit rates above 50 percent. The second factor is a recognition that as the population of smokers has evolved over the last 50 years, there are pockets of high prevalence and low cessation success that require new research funds to decrease these high pockets of prevalence. The National Institutes of Health has provided a model that has been used on a pilot basis – the establishment of Transdisciplinary Tobacco Use Research Centers (TTURC) – that can comprehensively target specific critical tobacco cessation research questions. These questions include identifying treatments that are effective in youth smokers, developing specific medications that might be helpful for specific populations, and identifying more effective treatment for low socioeconomic status, less educated, racial and ethnic minority smokers. The NIH TTURC model had been in existence for a couple years at a very limited number of Centers. In 1999, it initially funded seven very successful centers at a rate of $15 million per year for five years but that funding has been cut substantially. And because it was designed to pull together researchers built around a specific cessation target and to include components of translating the research findings into practice, the TTURC model represents our best hope to move tobacco dependence research forward in a substantial way. As a result, the Subcommittee concluded that by establishing 30 of these centers nationally at a cost of $450 million per year ($15

million/year/center) and administering them through a national coordinating center charged with bringing the findings together and disseminating them at a cost of $50 million per year, we would produce effective research results.

Q: Before we leave the subject of the research component of a national cessation program, let me ask why you believe we need additional research dollars beyond what is being expended by drug companies such as Pfizer and Glaxo to develop tobacco cessation pharmacotherapies?

A: The pharmaceutical industry has, of course, engaged in research into tobacco dependence treatments and in the last 15 years we have seen five new FDA-approved drugs after the initial approval of nicotine gum in the 1980s. Moreover, there are a number of potential new medications under study. But there are a lot of things that do not happen through the pharmaceutical industry. Take a look at youth smoking. Drug companies are extraordinarily reluctant to license drugs for children because of the risks or liability associated with it. So there is an enormous research gap on the subject of medications to treat adolescents who smoke. We see similar gaps within racial and ethnic groups. Native Americans are an example. As many as 40% of some tribes of Native Americans smoke, but because their numbers are relatively low, there is not a market for a pharmaceutical company to discover a treatment that might be particularly effective for the incredibly high prevalence rate we see among certain Native American tribes. Finally, the pharmaceutical industry doesn't develop evidence-based counseling strategies. Such counseling is key to ensure that smokers who can't take medication have treatment options and counseling methods exist to ensure that those smokers who use medication result in the highest quit rates. We need to meet these challenges.

E. Clinician Training and Education

Q: Let's turn now to the fourth component of the comprehensive smoking cessation program that you identified – "training and education to ensure that all clinicians in the United States have the knowledge, skills and support systems necessary to help their patients quit tobacco use." Please describe this feature of the integrated cessation program.

A: This, like all other parts of the comprehensive program, is closely linked to the other components. If we are going to invest in programs to improve no-barrier access to treatment, and to motivate smokers to try to quit smoking, we need to be sure that health care providers are educated and trained in the best evidence-based treatment strategies to address tobacco use and dependence. We want our healthcare professionals to make screening for tobacco use a routine part of their practice, and to give physicians the knowledge and tools to support their intervention with their patients to encourage quitting. We also want smokers to have effective treatment options. In addition to the proposed quitline, we want every smoker who visits a clinician each year to be provided with advice and assistance on quitting. And this is so important because 70% of smokers visit a primary care physician each year.

Q: How would this part of the program work?

A: The funds dedicated to training and education will be distributed as grants to medical and other healthcare professions schools to develop, implement, and evaluate curricula for evidence-based treatment of tobacco dependence for healthcare professions students. The goals of such training will be broad and will establish a standard of care for treating and referring patients who use tobacco. Curricular components will include how to intervene effectively with tobacco-using patients, how to implement systems changes to facilitate intervention, and how to access more intensive services for their patients.

These funds would also go toward working with healthcare professions organizations and licensing bodies to ensure that licensure and certification examinations for health professionals are modified to include assessments of knowledge on treatment of tobacco dependence.

The program would include grants to medical and health care profession schools to develop and evaluate advanced curricula for evidence-based treatment of tobacco dependence for specialists in the area of tobacco dependence treatment.

Finally, the program would have to include research to create and evaluate uniform standards for certification of tobacco dependence treatment specialists.

Q: What is the basis for your testimony that this clinician training and education is an effective tool to increase smoking cessation?

A: Seven out of ten smokers visit a physician every year. Few of them are provided with the evidence-based treatments as defined by the 2000 Guideline. If we consider the even broader reach of clinicians who smokers encounter -- dentists, nurses, physicians assistants, nurse practitioners -- more than 80 percent of smokers encounter a clinician each year. The Subcommittee, including the representative from the American Medical Association, Dr. Ron Davis and other physicians and clinicians on the Subcommittee, felt very strongly that unless we seize this teachable moment and intervene with smokers as they present to health care delivery systems, then we're not going to be able to drive down tobacco use rates in the way that Secretary Thompson charged us to achieve. And this is particularly salient given that many of these smokers are presenting to clinics with health problems directly caused by their tobacco use.

Q: What is the estimated cost for this clinician training initiative?

A: The total funding required for this training initiative is approximately $500 million per year, with half – $250 million – to fund training within the 145 accredited allopathic and

osteopathic medical schools in the U.S., and the other $250 million to fund training within other healthcare professional schools.

Q: On what is this cost estimate based?

A: The cost is based on the substantial experience of members of the Cessation Subcommittee in training clinicians in medical schools and elsewhere, including former Surgeon General David Satcher.

Q: Another aspect of a comprehensive cessation program that you identified as important is that it should "mobilize health systems to implement system-level changes that result in effective utilization of tobacco dependence treatments." Please describe this further.

A: Essentially, a comprehensive plan must include steps to ensure that our healthcare providers in all settings in which care is provided -- in both the private and public sectors whether that be in managed care organizations, in hospitals, in clinics, or elsewhere -- have systems in place that encourage clinicians to deliver effective tobacco dependence treatments. We want all healthcare delivery systems to make tobacco dependence treatment an integrated, essential part of the care they provide, by encouraging and providing the resources that will help these entities make systemic changes to incorporate tobacco dependence treatment part of their institutional framework.

Q: Please explain further about what a "system-level" change is and how it would come about as part of the comprehensive cessation program.

A: Traditionally, efforts to increase tobacco use intervention in the healthcare setting have targeted the individual clinician. However, to be truly effective, cessation interventions need broad support and participation from all stakeholders, such as managed care organizations,

hospitals, medical groups, health clinics and centers, throughout the healthcare system. There is a real need for technical assistance and funding to create, implement, and evaluate the office, practice, and organizational systems of care required for the delivery of evidence-based tobacco dependence treatments. As clinician training and research results in tobacco dependence treatment becoming routinely incorporated into health care delivery and representing the standard of care, I would expect healthcare delivery systems and organizations to take steps to fully and efficiently integrate this aspect of care at the institutional level.

Q: Have you estimated how much such systems-level changes would cost to develop, implement, and evaluate?

A: No. The Subcommittee did not receive reliable cost estimates for this component, so I have no reliable information on which to recommend a level of funding specifically for this initiative. But it is my expectation that these systems-level changes would occur as a result of the other components identified and discussed previously at the $5.2 billion annual funding level – including the training of clinicians and the comprehensive media campaign that will direct smokers to visit their healthcare provider.

Q: You also testified earlier that a comprehensive cessation program should "mobilize national quality assurance and accreditation organizations, clinicians, health systems, and others to establish and measure the treatment of tobacco dependence as part of the standard of care" and "mobilize communities to ensure that policies and programs are in place to increase demand for services and to ensure access to such services." How can this be achieved?

A: It is my opinion that these goals would also be achieved as a result of the other, funded initiatives that I recommend. For example, mobilization of communities should occur as a result

of the marketing campaign outlined in my testimony and by the Subcommittee in the National Action Plan.

Q: Dr. Fiore, have any of the recommendations of the Subcommittee on Cessation been implemented?

A: Not yet, as specifically recommended in the National Action Plan. However, HHS has taken two modest steps since the National Action Plan was presented to the ICSH.

Q: What are those steps?

A: First, in 2004, HHS announced a quitline initiative with total funding of approximately $25 million that was designed to do two things. About half of the money went to the National Cancer Institute to identify a toll-free number that would serve as a national quitline portal, linking smokers who want to quit to their state or regional quitlines, or in the absence of a state or regional line, provide limited counseling services. The other half went to CDC, which was charged with the responsibility of giving grants to states for a modestly increased level of telephone quitline counseling services. Of course, HHS recognized that the amount of money that was being distributed was so modest that there was no way this funding could even remotely provide the level of evidence-based quitline services recommended to the Court and that was recommended by the Subcommittee on Cessation.

Q: What was the second step?

A: This year, Medicare approved limited coverage for clinician-delivered smoking cessation counseling for Medicare beneficiaries with certain diseases or those on certain medications. The Subcommittee on Cessation had recommended full coverage for tobacco dependence counseling and medication treatment for all federal beneficiaries including Medicare recipients. So, this minor step, while laudable, is just a start.

Q: Dr. Fiore, what is the necessary length of time that a comprehensive cessation program must run?

A: Given the current size of the smoking population – about 45 million people, about 30 million of who tell us they want to quit – it is reasonable to expect that it will take as many as 25 or more years to allow every smoker in America who wants to quit to do so successfully. We know that 7 in 10 American smokers wants to quit smoking, but only about 2.5% are able to quit in any given year. This is true despite the fact that about 40% of smokers attempt to quit every year. *Reducing Tobacco Use: A Report of the Surgeon Geneeral* (2000) (JD 004673). Given the current prevalence of smoking, the number of new smokers who begin every year, and the number of smokers who die and who already stop smoking every year, the implementation of a national smoking cessation program can be expected to dramatically reduce the population of American smokers who want to quit. Again, this will be achieved by assisting one million additional smokers to quit every year as a result of the program. Without the program, smoking rates will decline at a much slower rate. This whole program is designed to provide evidence-based treatments to the great majority of smokers who are trying to quit and are currently not using such treatments. As a result, these motivated smokers who are quitting on their own are having extraordinarily low success rates. This program, based on the National Action Plan, will reach those people including some of the highest prevalence, hardest-to-reach smokers. It is designed to have a substantial immediate as well as sustained impact.

It is also necessary that a program exist for a long enough period of time to create the necessary environment in which the population is immune to misinformation about the health effects of smoking, and an environment that is conducive to long term success in achieving reductions in smoking prevalence. Over time, smokers will be made aware that, as a result of

this National Action Plan, it is as easy to get help quitting smoking as it is to walk down to the corner store and buy a pack of Marlboros.

Q: You have indicated that one million smokers will quit each year through the program. What is that number based on?

A: That is the number of smokers that we can help quit by means of the comprehensive quitline (counseling and medication) alone. It is a very conservative estimate, and is based on the Subcommittee's conclusion that approximately five million smokers each year can be expected to undergo treatment – counseling and medication – through the quitline. The estimated success rate of one million smokers per year is based on an extraordinary body of scientific evidence, including the 2000 Guideline and the Cochrane reviews, the CDC analysis, and others.

Q: You also indicated that the program should, over time, create an environment that is conducive to long term success in achieving reductions in smoking prevalence. Can you explain your answer for the Court?

A: Yes, I can. A smoker should have the knowledge of not only existing resources, but the value of those resources, when they want to quit. From my own experience treating more than 10,000 smokers in Wisconsin over the past 17 years, I know that every day people who are motivated to quit are making the tragic decision to switch to low tar cigarettes in the mistaken belief that they are taking a step for health. They are trying to quit "cold turkey" and failing. They are finding reasons to postpone quitting. All of these are decisions that should and can be prevented with a comprehensive program.

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